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Enforcement & Compliance Docket & Information Center

U.S. Environmental Protection Agency
Enforcement and Compliance Docket and Information Center
Mail Code 2201A
1200 Pennsylvania Avenue NW
Washington, DC 20460

Re: Docket No. EC-2000-007; Establishment of Electronic Reporting; Electronic Records; Proposed Rule ("CROMERR"); Federal Register of August 31, 2001 (66 FR 46162).

Dear Sir/Madam:

Provided below are the comments of the Pharmaceutical Research and Manufacturers of America ("PhRMA") on the recently published proposed Establishment of Electronic Reporting; Electronic Records ("CROMERR") regulation. PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier and more productive lives. Investing approximately $30 billion in 2001 in discovering and developing new medicines, PhRMA companies are leading the way in the search for cures.

EPA's proposed rule deals with both electronic reporting and electronic recordkeeping. Most of PhRMA's comments are concerned with the electronic recordkeeping portion of the proposal. In the preamble to the proposed rule, EPA stated that the recordkeeping provisions were intentionally modeled on the U.S. Food and Drug Administration (FDA) regulation at 21 CFR 11, which governs electronic recordkeeping in the pharmaceutical industry. EPA states at 66 Federal Register 46170 that, "The criteria set forth in today's proposed rule...are intended to be consistent with the criteria set forth for electronic document systems in other relevant regulations, such as the FDA's criteria in 21 CFR part 11." PhRMA member companies have been attempting to comply with these regulations since their promulgation. Thus, PhRMA is uniquely qualified to provide input to the discussion regarding the recordkeeping provisions of the CROMERR proposal.

Based on our experiences to date with the FDA regulation, PhRMA offers the following comments:

EPA is in error when it asserts that the proposed rule would be "voluntary" as regards recordkeeping

First and foremost, the EPA must learn from previous efforts to address electronic recordkeeping. The Food and Drug Administration and the pharmaceutical industry have both learned a painful lesson in the implementation of 21 CFR Part 11.

In the original 1994 proposal (59 FR 45160), FDA certified that the Electronic Recordkeeping rule would not have a significant economic impact because of the reduction in paperwork costs. In the 1997 final rule (62 FR 13430), the FDA expressed its continued belief that there would be an economic benefit from the rule due to reduced paperwork costs, stating that, because the rule was "voluntary," no company would implement the rule unless benefits exceeded costs.

For example, the FDA stated at 62 Federal Register 13462;

> The activities regulated by this rule are voluntary; no entity is required by this rule to maintain or submit records electronically if it does not wish to do so. Presumably, no firm (or other regulated entity) will implement electronic recordkeeping unless the benefits to that firm are expected to exceed any costs (including capital and maintenance costs). Thus, industry will incur no net costs as a result of this rule.

EPA mirrors these presumptions in the summary of CROMERRR (66 Federal Register 46162),

> "Under today's proposal, electronic document submission and record-keeping will be totally voluntary; EPA will not **require** the submission of electronic documents or maintenance of electronic records in lieu of paper documents or records." (Emphasis added.)

The FDA was mistaken in its belief that the original 21 CFR Part 11 rules could be considered completely "voluntary. " The agency failed to take into account the fact that major portions of the pharmaceutical business had been computerized by 1997 and were already relying on electronic records. Imposition of the 21 CFR 11 criteria, which then, and now, represented state-of-the art software development, onto all the existing electronic recordkeeping meant that essentially all of the electronic recordkeeping systems then in place would not comply with the new standards, and would require complete replacement.

Similarly, EPA is mistaken in its assertion that this rule would be "voluntary" as regards recordkeeping. Environmental records have been maintained in personal computer spreadsheets since such software was introduced in the early 1980's. Specialized

database programs have been on the market for years for such activities as Material Safety Datasheet management, Leak Detection and Repair program management, and refrigerant management. Indeed, EPA has frequently relied in rule development on data which was generated from these spreadsheets and later databases by industry for submission to the Agency. We believe it is likely that in calculating costs for administrative portions of most rules the EPA has presumed there will be electronic recordkeeping. Few, if any, of these spreadsheets and databases were constructed with anything like the CROMERR criteria in mind. Popular office software—Microsoft Excel, for example, simply does not have the audit trail capabilities CROMERR would require.

There has been no prohibition or other statement by the Agency that electronic recordkeeping was not allowed; while EPA's proposal discusses at length the Agency's past positions on electronic reporting, it is silent as to any historic EPA position on electronic recordkeeping. In fact, EPA's practical position on electronic recordkeeping has been to accept it as the routine fact of life that it has been for the last nearly 20 years. CROMERR's rather disingenuous pretence that electronic recordkeeping is something new, and therefore either readily malleable or voluntary in any way, can only lead, as the 21 CFR 11 rules have, to enormous costs and significant compliance roadblocks.

EPA has significantly underestimated the scope and cost to industry of complying with CROMERR in order to continue its current level of electronic recordkeeping.

EPA projects that the typical cost of "changing" to CROMERR-compliant recordkeeping at an average manufacturing plant would be about $40,000. This is generally consistent with the FDA's expected costs as stated during development of 21 CFR 11. Although even at that time PhRMA believed these cost estimates were too low, PhRMA's own estimates were much, much less than the reality.

The real implementation costs for 21 CFR 11 have exceeded all original predictions. At this time, the projected cost to a medium to large pharmaceutical company is in excess of $100 MM for legacy system remediation and new system implementation. The industry as a whole is spending more than $1 billion to achieve compliance. This does not take into account the incremental increase in cost for purchasing new, compliant systems instead of continuing to use older, but still quite functional, data systems.

One of the largest cost factors and complexities with implementation of the Part 11 rules has been related to upgrading of existing systems. Redesign, modification, testing and validation of existing systems have been a major undertaking. Retrofitting functionalities into an existing system is often more expensive and more time consuming than building the requirements into the system in the first place. Thus, the appropriate compliance

choice for many existing systems will be complete replacement. EPA needs to take these wholesale replacement costs into account.

In addition to simple system replacement costs, EPA's estimates of implementation and operation costs clearly do not take into account the complexity associated with interconnected, complex systems and validation of those systems.

A number of key factors have contributed to the costs of compliance with Part 11 requirements within the pharmaceutical industry, including:

1. Companies have large numbers of systems covered by the rule. In the case of major pharmaceutical companies, this can comprise several hundred systems. Environmental recordkeeping at a large site could easily involve as many systems.
2. Systems are strongly interconnected so that changes made to a given system have broad implications requiring extensive testing and validation across all systems.
3. Commercial software packages used in the industry often lacked the functionality required by the regulation and it is taking significant time (on the order of several years) for vendors to incorporate the required functionality into their products.
4. The rapid pace of change of technology makes it difficult to provide secure long term archiving of data in electronic form.

Based on its own experience with 21 CFR 11, and based on its own companies' knowledge of the environmental recordkeeping they now do electronically, PhRMA sees every reason to expect that the cost for a typical manufacturing company to conform to CROMERR, for the required environmental records it already keeps electronically, will be orders of magnitude higher than the $40,000 EPA is predicting. As pharmaceutical manufacturing operations make up only a tiny part of the total manufacturing capacity of the United States, it is reasonable to predict that the total actual cost to implement CROMERR, even for only those activities now being electronically recorded, will be far in excess of the more than $1 billion that 21 CFR 11 has already cost the pharmaceutical industry.

Reference is made to comments in the FDA docket submitted by the Pharmaceutical Research and Manufacturers of America (PhRMA) representing industry-wide impacts as well as comments submitted by PhRMA on October 29, 2001 to Mr. John Taylor, Director of the Office of Enforcement, Food and Drug Administration, regarding the scope and implementation of 21 CFR Part 11. Each of these documents describes in greater detail the pharmaceutical industry experience with implementing electronic reporting and recordkeeping using the FDA model.

EPA fails to provide a convincing rationale for the need to impose the proposed requirements on electronic recordkeeping.

EPA indicates in the CROMERR proposal that it has three goals in this proposal that would "allow electronic ... recordkeeping": reduce cost and burden of data transfer and maintenance; improve the quality of the data; and maintain or improve the level of corporate and individual accountability. As discussed above, the Agency has clearly failed to reduce cost and burden with this proposal. Similarly, the Agency has failed to demonstrate in this proposed rule, or elsewhere, that there are such significant and wholesale problems with either the quality of existing electronic records, or with the level of corporate and individual accountability that they warrant such wholesale and burdensome remedial measures. Nor does EPA's proposal present evidence that the measures proposed would truly meet those goals.

EPA has failed to consider the technological obstacles now existing to implementation of its proposed recordkeeping rule.

The technological challenge of data retention has not yet been solved. Many environmental regulations require that records be maintained for longer than the typical 5-year life cycle now common in information technology. Newer systems generally lack the capability to read from older databases. Thus, it is difficult to guarantee that information, once recorded, can be restored for more than about 5 years. And going from the records back to the system that produced them will be even more difficult. In October 29, 2001 comments on FDA's proposed Guidance on the Scope and Implementation of 21 CFR Part 11, PhRMA notes that "The goal of being able to restore not only the data, but also the system that processed it is an even greater challenge that is probably not achievable in the current technical environment." EPA needs to consider these technological limitations in its proposals for electronic recordkeeping.

The CROMERR rule as currently proposed is a disincentive to electronic recordkeeping.

Currently, many computer systems are used to obtain and store data of environmental interest. The costs of compliance with CROMERR, especially where the data go into a broad manufacturing management system, are such that the rational choice for many data points at many sources will be a return to hand recording, visual chart interpretation, and similar practices, all proven to be fraught with opportunities for human error. Rather than improving on electronic recordkeeping, EPA will encourage companies to continue with, or return to, the known imperfections of human recordkeeping. EPA's mandate, from the Government Paperwork Elimination Act (GPEA) of 1998, is to encourage, or at least not to discourage, electronic recordkeeping. CROMERR would have exactly the opposite effect.

Summary and Recommendations

PhRMA's experience with the electronic recordkeeping requirements of 21 CFR 11, which EPA has used as a model in developing the CROMERR proposal, shows that EPA has seriously underestimated the scope, the cost, and the feasibility of its proposed approach to electronic recordkeeping. EPA has also failed to demonstrate that any solid, positive, quantifiable value would be obtained by implementing the CROMERR recordkeeping requirements. Thus, PhRMA recommends that EPA withdraw the proposed rule and reconsider whether its objectives may be met in some other way. PhRMA recommends EPA take a limited approach to fulfilling its requirements under the GPEA by specifying its standards for electronic signatures, and take no action regarding existing electronic recordkeeping practices. If EPA wishes to consider further how best to enhance the quality of environmental recordkeeping, PhRMA recommends that EPA should assemble its concerns, and the data supporting them, and present these for public discussions to gather input on appropriate courses of action.

PhRMA appreciated the opportunity to provide comments on this proposal We hope these comments are helpful in EPA's further evaluation of electronic recordkeeping and reporting.

Sincerely,

Alice E. Till, Ph.D.